

MEETING THE MILLENNIUM DEVELOPMENT GOALS – the Pan-African Clinical Trials Registry

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INTRODUCTION

The Pan African Clinical Trials Registry (PACTR) (www.pactr.org) is the first and only World Health Organization-endorsed primary prospective trials register in Africa (see Box 1). The PACTR is led by the South African Cochrane Centre (SACC), Medical Research Council, in partnership with the Cochrane Infectious Diseases and Cochrane HIV/AIDS Review Groups, and funded by the European and Developing Countries Clinical Trials Partnership.

The PACTR aims to:

1. Provide a platform for prospective registration of clinical trials conducted in Africa;
2. Promote prospective registration of all trials conducted in Africa; and
3. Provide a publicly accessible, free, searchable database of all trials conducted in Africa,

Our objective in this poster is to demonstrate how the PACTR can provide a useful mechanism for monitoring the Millennium Development Goals (MDG), especially MDG 4 (to reduce by two-thirds, between 1990 and 2015, the under-five mortality rate) and MDG 6 (Target A: to have halted by 2015 and begun to reverse the spread of HIV/AIDS; Target B: to achieve, by 2010, universal access to treatment for HIV/AIDS for all those who need it; Target C: to have halted by 2015 and begun to reverse the incidence of malaria and other major diseases).

METHODS

We downloaded full trial data for every trial application captured on the PACTR on 12 November 2009. Two investigators independently extracted trial data using a standardized data form. Extraction fields included the disease type, intervention type, age of recruited participants and trial location. Particular attention was paid to how the trial landscape reflected efforts to meet MDGs 4 and 6, and how PACTR could contribute to these MDGs.

RESULTS

General:

Since the establishment of PACTR in 2007, we have received 31 applications for trial registration, with 12 of these meeting registration requirements. Thirteen applications were ineligible due to the study design being other than a clinical trial (3) or application received post commencement of the trial (10). Currently six applications are incomplete.

Millennium Development Goal 4:

To reduce by two-thirds, between 1990 and 2015, the under-five mortality rate

Two of the 12 registered trials explore prevention or alternative treatments for Malaria or Tuberculosis (TB) in children. Three assess the interventions to reduce mother-to-child transmission of HIV. Thus, five of 12 (42%) registered trials align with MDG 4's bid to reduce child mortality.

Millennium Development Goal 6:

A: To have halted by 2015 and begun to reverse the spread of HIV/AIDS

B: To achieve, by 2010, universal access to treatment for HIV/AIDS for all those who need it

C: To have halted by 2015 and begun to reverse the incidence of malaria and other major diseases

Six of 12 (50%) registered trials explore interventions for Malaria (1 trial) or HIV/AIDS (5 trials), the two named diseases that MDG 6 is tasked with combating. All five HIV/AIDS trials evaluate prevention interventions and the Malaria trial evaluates treatment. Of the remaining six registered trials, three investigate TB treatment, two research comorbid HIV/AIDS and TB treatment and one investigates hyperkalaemia.

DISCUSSION:

What did we find?

This is the first analysis of trials currently registered in the PACTR since it was launched as a WHO-endorsed primary registry in September 2009. Although trial numbers are limited, this first analysis of currently registered trials reveals a focus on HIV/AIDS prevention, and on trials developing interventions aimed at children.

What does the PACTR add?

Although current registration numbers do not reflect the actual number of trials underway in Africa¹, our analysis demonstrates that as the PACTR grows and becomes more comprehensive, it can provide a useful mechanism for monitoring research towards achieving MDGs 4 and 6. Regular analysis of the PACTR's data can assist by tracking trial activity on the continent. By searching for age of participant or disease (both possible in the PACTR), the database can provide longitudinal data on the development of efforts to combat child mortality and the diseases that most burden the African continent² (AIDS, TB and Malaria).

What does the future hold for the PACTR?

PACTR staff are working further to achieve MDG 4 through our involvement with a WHO-funded project aimed at the development of a child-focused strategy to increase trial registration (see Box 2).

CONCLUSION

By providing a free registry and a searchable repository of African trials, the PACTR contributes to the research required to achieve MDGs 4 and 6 by allowing the changing landscape of knowledge on these diseases to be monitored.

Box 1

What does it mean to be a WHO-endorsed primary registry?

A clinical trials registry is a database in which key administrative and scientific information about planned, ongoing and completed trials, sufficient to identify that trial's existence, are stored.

Primary registry status is granted by the WHO only to registries that meet specific criteria for content. Criteria are separated into six categories, namely, content, quality and validity, accessibility, unique identification, technical capacity and administration and all categories must be met in order to receive Primary Registry Status. WHO Primary Registries meet the requirements of the International Committee of Medical Journal Editors (ICMJE) which stipulate that, in order to be published in a member journal, registration is mandatory.

Thus registration with a WHO-endorsed primary registry is critical for dissemination of trial results.

What are the benefits of registering a trial?

- Reduces publication bias
- Fulfills researcher's ethical obligation to research participants
- Ensures transparency and enhance public trust in the conduct of clinical research
- Increases participant enrollment in research trials
- Reduces duplication of research and limited resources

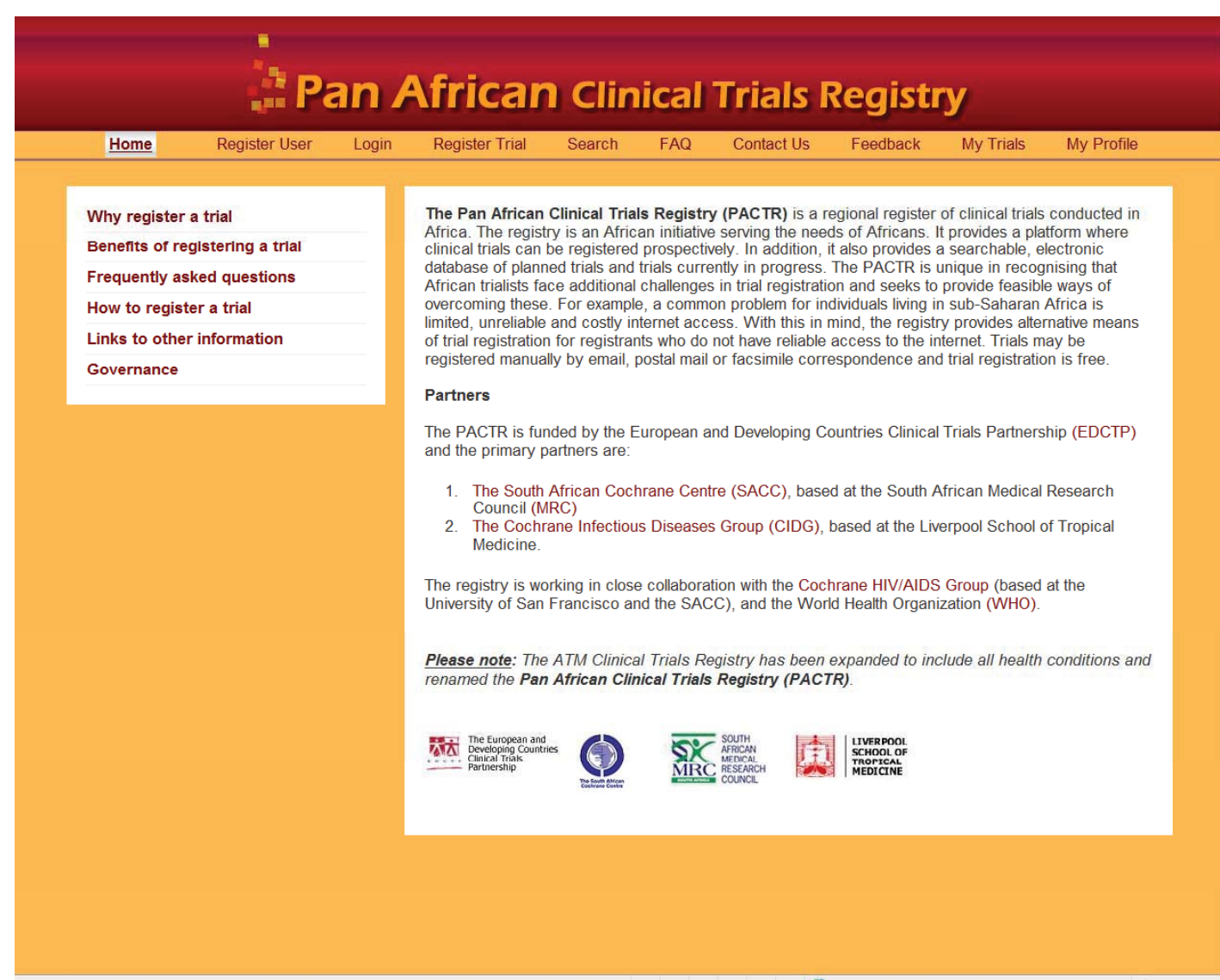
So, why register with the PACTR?

- PACTR's WHO-endorsed primary registry status allows researchers in Africa to register their trials with PACTR as the registry of choice for the African region. PACTR feeds into the global WHO International Clinical Trials Search Portal (www.who.int/trialsearch/), ensuring African representation in the global picture of planned, ongoing and completed clinical trials.
- Registration is free, and information on registered trials is easy to search and free to access.

Box 2

A Child-Focused Strategy

The South African Cochrane Centre has also just embarked on a project to develop a strategy to achieve the increased registration of clinical trials recruiting children in Africa. This is part of a larger World Health Organization initiative to increase registration of child-focused trials throughout the world. Over the next three years the South Africa Cochrane Centre will gather information on key actors and networks that attend to children's health on the continent. With the help of these key players and networks, we will establish a list of organizations, conferences and venues to disseminate the strategy and increase awareness of the initiative. Using the PACTR, a prospective database of child-focused trials will be developed. In addition, attempts to develop a retrospective database assessing the child-focused trial landscape on the continent will be undertaken. This three-year project will culminate in a collaborative conference where invited key players, networks, research groups, etc., will convene and discuss the continuation of the strategy and future objectives in maintaining high levels of trial registration, particularly in child-focused research.



A screen shot of the PACTR's homepage

Registration is Easy!

But, if you have any problems, please do not hesitate to contact PACTR staff:

- Site: www.pactr.org
- Email: pactradmin@mrc.ac.za
- Telephone: +27 (0)21 938 0506
- Postal Mail: PACTR c/o SACC at MRC
PO Box 19070
Tygerberg 7505
Cape Town, South Africa

The final slide from the power point presentation "How to Register with PACTR"

¹ WHO. Third Meeting of the African Vaccine and Regulatory Forum (AVAREF) Report. 28 – 31 October, 2008. (www.who.int/immunization_standards/.../third_avaref_report160409.pdf) Site accessed November 19, 2009.

² See "Africa leaders announce new resolve to combat HIV/AIDS, TB, Malaria", WHO-AFRO press release Site accessed November 19, 2009, (<http://www.afro.who.int/press/2006/pr20060505.htm>)

